EXHIBIT I

DIROS TECHNOLOGY INC

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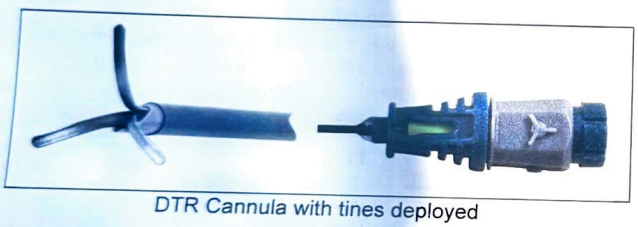
INSTRUCTIONS FOR USE

OWL STERILE SINGLE USE TRIDENT™ RF INSULATED CANNULA, MODEL DTR

(EACH DEVICE IS PROVIDED IN A STERILE POUCH, *SOLD IN BOX OF 10*)

Introduction:

Diagram 1
OWL Sterile Single Use Trident™ RF Insulated Cannula, model DTR. (Protection Tube is not shown)



DTR Cannula with tines deployed

DTR Cannula with tines retracted

Diagram 2
DTR cannula tip with tines deployed and tines retracted. Tines deployment and retraction are indicated on the hub/handle.

The OWL Sterile Single Use DTR Cannula is constructed from stainless steel tubing. Cannulae consist of partially insulated shaft, plastic hub/handle and cap with stylet. The Cannula hub/handle is equipped with a mechanism that allows deployment and retraction of 3 tines.

⚠ WARNING

- The OWL Sterile Single Use DTR Cannula is manufactured for use only with OWL RF Generators.
- Do not modify this device in any way shape or form.
- It is important to use the correct size lesion/temperature probe (i.e. the probe/cannula combination)
- The RF Probe/Temperature Sensor must be inserted fully into the insulated cannula, otherwise the measured temperature will be incorrect.
- Ensure that the R.F. Probe/Temperature tip does not protrude from the bare tip of the insulated cannula, as the resulting lesion will be larger than intended (see Figure 2)

CAUTIONS:

- If for any reason the insulation on the cannula is damaged, it should not be used there will be a risk of creating unwanted lesions. Therefore, it is very important that prior to each operation to visually inspect the cannula to ensure that the insulation is intact.
- Always use the 5 cm DTR cannula with the 5 cm R.F. Probe/Temperature Sensor.
- Always use the 10 cm DTR cannula with the 10 cm R.F. Probe/Temperature Sensor.
- Always use the 15 cm DTR cannula with the 15 cm R.F. Probe/Temperature Sensor.
- Always use the 20 cm DTR cannula with the 20 cm R.F. Probe/Temperature Sensor.

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Contents

1. Important Information - prior to use, note the following:

- *Carefully* read all instructions in this document prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to properly follow instructions may lead to improper functioning of the device and may result in patient injury.
- In addition, read, understand, and follow the full information provided in the instructions for use for other devices intended to be used with this device.
- Keep all literature for future reference.
- By law, this device is restricted to sale by or on the order of a physician.

⚠ WARNING

IN THE INTEREST OF PATIENT SAFETY –
This product has been carefully fabricated to accepted standards and should be handled with care.
Under no circumstances should an effort be made to straighten or repair any other component of the device. If any component is damaged in any manner, it should be discarded.

- *OWL Sterile Single Use TRIDENT™ R.F. Insulated Cannulae are packaged as disposable, SINGLE USE for a single patient, EO STERILE.*
- *Device should be used only by a trained physician.*
- *Use device only with the correct length RF Probe/Temperature Sensor*
- *Do not re-use or re-sterilize.*
- *Do not bend the cannula.*
- *Do not modify this device in any way shape or form.*
- When package is broken or dirty or if the insulation is damaged, cracked, peeling, chipped, cut, missing, DO NOT USE AND DISPOSE OF THE PRODUCT IMMEDIATELY (refer to disposal section for details) to prevent injury. Failure to properly follow instructions may lead to improper functioning of the device and may result in patient injury. of the device and may result in patient injury.

2. Indications for Use

The OWL Sterile Single Use TRIDENT™ RF Insulated Cannula, may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

Contraindications: Radiofrequency treatment is contraindicated on patients with a cardiac pacemaker, implanted defibrillator, implanted neurostimulator, or any active electrical implant.

Caution: There is insufficient clinical data demonstrating safe and effective use of radiofrequency treatment in pediatric and pregnant patient populations.

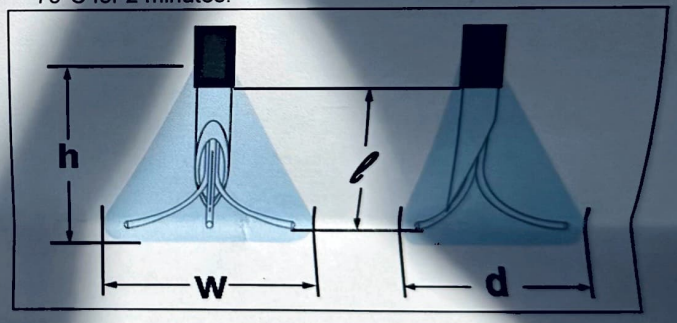
RF procedures should be reconsidered in persons with poor psychological capacity, and among those receiving anticoagulation therapy or with anticoagulopathy.

Avoid use on infected areas. Do not reuse the device if used in an infected area or among persons with systemic infections.

3. Selecting a Cannula for Use

- Select a length based on the location of treatment. Obese patients may require longer cannulae to access treatment areas.
- Select active tip length and gauge based on the size of the lesion desired. A longer active tip produces a longer lesion and a larger diameter produces a wider lesion[1]. The following data shows the effect of the characteristics of the cannula on lesion size.
- For large tip sizes longer ramp time is recommended.

The data in table 1 below show the predicted lesion size at 75°C for 2 minutes.



Needle Gauge	Active Tip Length (ℓ) (mm)	RF Lesion at 75°C for 2 minutes		
		Height (h) (mm)	Width (w) (mm)	Depth (d) (mm)
20	5.0	8.1	7.3	6.8
20	10	13.0	7.5	7.1
18	5.0	9.1	7.6	7.6
18	10	13.3	7.7	7.8
17	6.0	9.7	8.2	7.9
17	10	13.6	8.7	8.5

Table 1 Predicted lesion size corresponding to needle gauge and active tip length. The information provided above is based on preclinical ex vivo testing on non-perfused tissue utilizing direct visual measurement of the lesion (not thermal imaging). Please note lesion size is also dependent upon the duration of

[1] Organ, L.W. *Electrophysiological Principals of RF Lesion Making*, Applied Neurophysiology 19:69-76 (1976/77)

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exposure and the particular temperature chosen. Lesion sizes produced with the Trident device should not be assumed to be equivalent to those of other RF cannulae.

⚠ WARNING

- It is important to use the correct size lesion/temperature probe (i.e. the probe/cannula combination)
- The RF Probe/Temperature Sensor must be inserted fully into the insulated cannula, otherwise the measured temperature will be incorrect.
- Ensure that the Lesion/Temperature Probe tip does not protrude from the bare tip of the insulated cannula, as the resulting lesion will be larger than intended.
- Radio-frequency procedures should be performed in a fully-equipped operating room environment and only by physicians who are thoroughly trained in RF procedures.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the instrument is in use.
- When an RF Generator and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating HF current limiting devices are recommended.
- The patient leads should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
- The interference produced by the operation of an RF Generator may adversely influence the operation of other electronic equipment.
- Malfunction of an RF Generator could result in an unintended increase of output power; therefore, supervision of the equipment during procedure is required. Application of RF energy may cause undesirable neuromuscular stimulation.
- Use the correct size return path electrode to avoid burns at this site. Generally, it should be at least 20 times the area of the bare tip. Refer to OWL RF Generator Operator's Manual for complete details.

Only for use with DIROS/OWL products

- *Cannula maximum rated voltage is 150Vrms at 480kHz*
- *Avoid output settings of generator exceeding this voltage*
- *OWL RF Cannulae should not be used with generators, electrodes, temperature sensing probes or any other components of any manufacturer other than Diros Technology Inc. This warning must be followed to avoid possible harm to the patient or damage to the equipment.*
- Use only genuine OWL components manufactured by Diros Technology with the OWL electrode sets.
- Use of components not of Diros Technology manufacture together with Diros Technology equipment may seriously compromise the safety of the patient and efficiency of the equipment.

⚠ WARNING

PATIENTS WITH PACEMAKERS, IMPLANTED DEFIBRILLATORS, OR ANY ACTIVE ELECTRICAL IMPLANT:
Radio-frequency lesion generation equipment should not be used on a patient with a cardiac pacemaker, implanted defibrillator, implanted neurostimulator, or any active electrical implant.

⚠ WARNING

MRI SAFETY INFORMATION
The OWL Sterile SINGLE USE Trident™ R.F. Insulated Cannulae are MRI Unsafe.

4. Return Path Electrodes

RECOMMENDATIONS FOR RETURN PATH (GROUND, REFERENCE) ELECTRODES

The return path (also termed ground, reference, indifferent, neutral or dispersive electrode) electrode serves to complete the current path through the patient. Current from the RF generator is applied to the patient through the uninsulated portion of the lesion electrode. It must find a return path back to the RF generator and does this through the return path electrode; otherwise no current could flow. Therefore, RF current always passes through both the lesion electrode and the return path electrode, and it is important to be aware that tissue heating can occur equally well at either electrode if current density (the amount of current per unit area) is high. It is essential that current density at the return path electrode remains low to avoid excessive heating and burns at this site. Burns can be avoided if the effective contact area of the return path electrode is much larger than the bare surface of the lesion electrode. The effective contact area, is the area of the electrode that is actually in contact with the skin.

Important guidelines for proper use of return path electrodes:

⚠ WARNINGS

Patient or operator injury can result from improper handling of the OWL Universal RF System and the indifferent (dispersive) electrode, particularly when operating the device.

- The subject should be asked after the first lesion is applied, and periodically thereafter, if any sensation of warmth or other discomfort was felt during or after lesion making.
- The electrode surface should be in firm contact with the skin, and periodically observed to ensure that no part of it has lifted off, thereby decreasing its effective contact area.
- The effective contact area of prejelled fabric-backed disposable electrodes must be a minimum of 50 sq. cm. The electrode should be freshly opened from its sealed packet, and moistness of the embedded conductive jelly should be confirmed. The use of disposable ECG monitoring electrodes is not recommended.
- Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.
- The entire area of the neutral electrode should be reliably attached to a suitably prepared and appropriate area of the PATIENT'S body.
- Do not place return path electrode over: scars, bony prominences, hairy skin, prosthesis or ECG electrodes.
- Apparent low output or failure of the HF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power. Then the application of the **return path electrode** and its connections should be checked before proceeding.
- It is important to be aware that tissue heating can occur equally well at either electrode if current density (the amount of current per unit area) is high. Use properly sized patient return electrodes.

Recommendation: The OWL GD-Pad Disposable Patient Return Electrode should be used with the OWL RF Generators. The operator should rely on the instructions for use provided by the manufacturer of the PATIENT RETURN ELECTRODE for specific placement instructions.

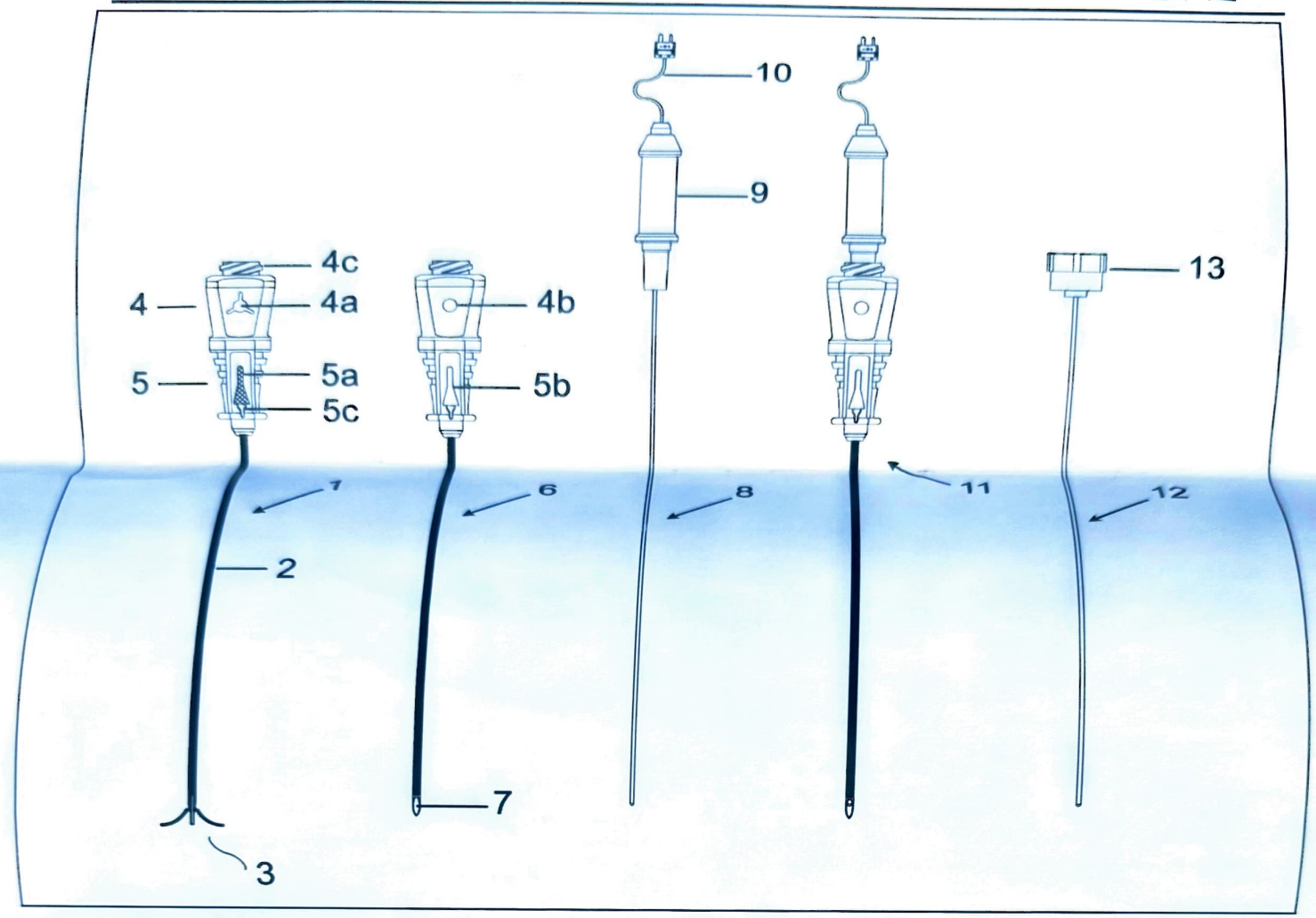

Figure 1. OWL Single Use Trident™ RF Insulated Cannula model DTR. *(RF Probe/Temperature Sensor supplied separately)*

5. Trident RF Cannula Components

1 The Trident™ RF Insulated Cannula with tines completely deployed.

2 Insulated shaft of the Trident™ RF Insulated Cannula.

3 The 3 tines deployed.

4 Rotatable Actuator of the Trident™ RF Insulated Cannula

- ***4a** Forward-facing "3-tine" symbol indicating that clockwise Actuator rotation has fully deployed the tines.*
- ***4b** Forward-facing "0-tine" symbol indicating that counterclockwise Actuator rotation has completely withdrawn the tines into the cannula.*
- **4c** Threaded top section of the Actuator that accept the Cap (**13**) of Stylet (**12**).

5 Hub of the Trident™ RF Insulated Cannula.

- **5a** Viewing Window for indicating tine deployment by a slider within the Window. As shown, the green slider (See Diagram 2) fills the window when the tines are fully deployed.
- **5b** The Slider is not visible, indicating that the tines are completely withdrawn into the cannula.
- **5c** Marker Tab indicating the direction of the open face of the cannula (needle) bevel.

6 The Trident™ RF Insulated Cannula with tines completely withdrawn into the cannula.

7 Bevel of the Trident™ RF Insulated Cannula.

8 RF Probe/Temperature Sensor.

9 Handle of the RF Probe/Temperature Sensor.

10 Cable and Plug of the RF Probe/Temperature Sensor.

11 Showing RF Probe/Temperature Sensor (**8**) completely inserted into the Trident™ RF Insulated Cannula (**6**).

12 The Stylet for insertion into the Trident™ Insulated RF Cannula (**1, 6**).

13 Cap of the Stylet.

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6. Directions for Use

6.1 Equipment Required

Radiofrequency lesion procedures should be performed in a specialized clinical setting with fluoroscopic equipment.

The RF equipment required for the procedure is as follows:

It is important to use the correct size lesion/temperature probe

Q-ty	Equipment			
1	OWL Sterile Single Use Trident™ RF Insulated Cannula, model DTR			
1	OWL RF Probe/Temperature Sensor. Use probe of matching length. (i.e. 5cm DTR cannula with 5cm probe)			
	D466-005	D467-005-TC	D467-005-TCH	5cm probe
	D466-010	D467-010-TC	D467-010-TCH	10cm probe
	D466-015	D466-015-TC	D466-015-TCH	15cm probe
	D466-020	D466-020-TC	D466-020-TCH	20cm probe
1	Corresponding connecting cable			
	For probe models		Cable models	
	D466-005, D466-010, D466-015, D466-020		463-103-TM-S, 463-103-S, 463-103-S (IEC),	
	D467-005-TC, D467-010-TC, D466-015-TC, D466-020-TC		H4-S2F-S, 463-103-HCT-S	
	D467-005-TCH, D467-010-TCH D466-015-TCH, D466-020-TCH		H4-H4-S, 463-103-TCH-S, 463-103-BPTCH-S	
1	OWL Radiofrequency generator, URF-3AP			
1	OWL Disposable Indifferent dispersive electrode (GD-Pad) meeting ANSI/AAMI standard HF-18 requirements for electrosurgical electrodes, models D7506, D7506NC			

6.2 Equipment Inspection Prior To Use

Devices are supplied in a sterile pouch 1 device per pouch.
Device does not require assembly prior to use.
Pouch contents:
1pc Trident™ RF Insulated Cannula (with protection tube)

The device does not require assembly prior to use
Perform the following checks before the patient is presented for the procedure. These tests will allow you to verify that the equipment you will use is in proper working order.
Do these tests in a sterile environment.

- **Package integrity**

Inspect the pouch for any signs of damage that may compromise the sterility of the contents. Check the expiration date of the device and do not use if it is past expiration date.

- **Shaft and Cable Insulation**

The insulation/coating for all devices should be visually inspected before each procedure. Inspect for cracked, peeling, chipped, cut, missing or otherwise damaged insulation. If detected, device must not be used to prevent personal injury for both patient and user. Such damage could lead to exit of RF current at a point along the shaft, producing unwanted tissue heating there and possibly burns. Cable insulation for both active and dispersive electrode cables should be checked prior to each procedure to be sure it is not damaged or cut. Regularly inspect and test re-usable cables and accessories

- **Mechanical Damage**

Inspect the device for any mechanical damage to the shaft, tines, hub/handle, cable or the connector.
Inspection should also include the accessories that will be used with the device.
If damage is detected, device must not be used to prevent personal injury for both patient and user.

6.3 Procedure

1. Assemble all required equipment for the intended procedure and position the patient as necessary.
2. Attach the Return Path Electrode (GD-Pad). Read and follow the manufacturer's instructions for use of the GD-Pad electrode to determine proper placement. Always use return path electrodes that meet or exceed ANSI/AAMI HF-18 requirements.
3. Inspect the part number of the RF Probe/Temperature Sensor to ensure that it is the correct length to match the length of the Trident™ RF Insulated Cannula.
4. Test the match by removing the stylet from the cannula and slowly inserting the RF Probe/Temperature Sensor into the cannula. Do not use excessive force to avoid damage to the RF Probe. The tip of the RF probe must lie within the bare tip of the RF cannula, see Figure 2. Otherwise the measured temperature will be incorrect. To further verify this, note the position of the handle of the RF Probe, Figure 1 (**9**) relative to the threaded top section of the Actuator, Figure 1 (**4c**). Then remove the RF Probe from the RF Cannula, place it parallel to and alongside the cannula and confirm that the tip of the RF Probe is no more than a mm short of the end of the RF Cannula bevel, but does not extend beyond it. Reinsert the Stylet into the RF Cannula.
5. Connect the plug of the intermediate cable to an input of the Multi-Lesion Adaptor or to the Probe receptacle on the RF Generator. Maintain access to the probe connection end of the intermediate cable in order to facilitate easy attachment to the RF Probe/Temperature Sensor to it.

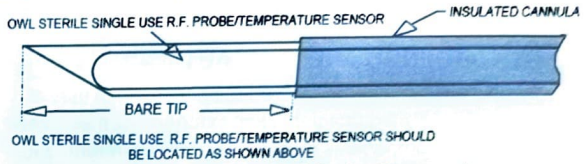

Figure 2. Correct position of RF Probe/Temperature Sensor within the Trident™ RF Insulated Cannula. Tines are not shown.

6. Re-insert the stylet into the Trident™ RF Insulated Cannula and ensure that the tines are fully withdrawn into it. A distinct click will be heard to indicate full withdrawal. Following superficial anesthesia hold the cannula *only* by its hub (not by the actuator) and insert it into the patient at a predetermined skin site and, using fluoroscopic guidance, position the active tip at the desired lesion location.
7. Once the cannula is properly positioned carefully remove the stylet from the cannula and insert the full length of the RF Probe/Temperature Sensor down the shaft of the Sterile Single Use Trident™ RF Insulated Cannula.
8. Plug the probe connector to the probe connection of the intermediate cable. Check if device is reading room temperature before placing it into a patient.
9. If proper connection is made, then the RF Generator should read within correct ranges of impedance and body temperature. Otherwise check all connections listed above.
10. Apply sensory and/or motor electrical stimulation as indicated by your protocol to verify correct electrode placement. If the results of stimulation are not acceptable and repositioning of the cannula is required, first fully withdraw the tines into the cannula and then reposition. Repeat electrical stimulation as indicated.
11. Lesion as necessary. Refer to the RF Generator User's Manual for more information. Upon completion, remove the RF Probe/Temperature Sensor and instill anesthetic and steroid if in accordance with your protocol. When connecting/disconnecting the RF Cannula to the syringe, ensure once again to grasp the cannula only by its hub. Upon completion of the procedure, remove the Trident™ RF Insulated Cannula (with RF Probe/Temperature Sensor still in it if no anesthetic applied).
12. Dispose of single use products properly.

⚠ ***Important notes:***

- Tines must be fully deployed before stimulation, otherwise results will be erroneous.
- If tines are not fully deployed the resultant lesion will be smaller than expected.

- *If cannula tip is in a close proximity to the bone and/or in a deep/acute of an angle; tines may not fully deploy and resultant lesion will be smaller than expected.*
- *Fully withdraw tines before repositioning the device*
- *Immediately stop any movement of the device if resistance is noticed.*

6.4 Potential risks and complications

Potential Risks with RF Neurotomies

In general, no mortality or permanent severe morbidity. However, with any operative procedure the following can uncommonly occur:

- Infection.
- Bleeding or hematoma along the cannula tract.
- Local, regional, or systemic adverse to drugs used during the procedure—local anesthetics, analgesics, and steroids.

In general, with RF procedures:

- Skin burns from reduced area of contact of return path electrode either from use of return path electrodes with too small surface area or accidental partial loss of surface contact area.

⚠ WARNINGS AND PRECAUTIONS

Inspect all components for damage prior to each use. If components are damaged in any manner they must not be used. Damaged components must be discarded or returned for evaluation/repair. Damaged components may result in patient or operator injury.

- Check if device is reading room temperature before placing it into a patient
- Do not start treatment without verification of correct placement
- Do not start treatment if device doesn't read body temperature and impedance
- Do not move device during treatment
- The RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the Probe and GD-Pad electrode, particularly when operating the device.
- Malfunction of the RF Generator could result in an unintended increase of output power; therefore, supervision of the equipment during a procedure is required.
- Radio-frequency procedures should be performed in a fully-equipped operating room environment and only by physicians who are thoroughly trained in RF procedures.
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the area where the instrument is in use.
- During RF power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
- When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
- The patient leads should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
- Use the correct size return path electrode to avoid burns at this site. Generally, it should be at least 20 times the area of the bare tip. Refer to OWL RF Generator's Manual for complete details.
- Application of RF energy may cause undesirable neuromuscular stimulation.
- During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
- Set RF generator in monopolar mode of operation.
- Use the correct size return path electrodes to avoid burns at this site. (Refer to information in section Return Path Electrodes)
- The interference produced by the operation of RF Generator may adversely influence the operation of other electronic equipment.
- When this device is used with RF Generator, care must be taken when operating around other equipment to avoid reciprocal interference. Potential non- ionizing electromagnetic or other interference could occur to this or to the other equipment near it.

⚠ WARNING

These devices are intended for single use only. Re-using this product will cause:

Cross-Patient Infection	Biofilms, biological materials, pathogens, prions (CJD) etc can be left on the device. No method of sterilization after use has been validated for single use products.
Pyrogenic Reactions	Single use devices can be contaminated with endotoxins that can cause pyrogenic reactions. Biocompatibility of devices has not been evaluated after use.
Compromised function and effectiveness of devices	Determination of materials from use, exposure to chemicals, heat etc may degrade the performance of the device and compromise its effectiveness.
Toxicity of reprocessing chemicals	Biocompatibility and toxicity of device has not been evaluated after reprocessing. Reprocessing can result in residual toxicant levels to which subsequent patients may be exposed.

7. *Storage*

Keep away from extreme temperature, humidity and direct sunlight. Store in a cool, dry place.

8. *Disposal*

Dispose of components according to proper protocol for biohazardous products.
Devices infected with Creutzfeldt-Jakob disease (CJD, vCJD) agents must be discarded according to the guidance of the World Health Organization (WHO) and country specific regulations.

9. *Product Information Disclosure*

Diros Technology Inc. has exercised reasonable care in the manufacture of this product. Diros Technology Inc. excludes all warranties, whether express or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness, since handling and storage of this device by the user, as well as factors relating to the patient's diagnosis, treatment and other matters beyond Diros Technology Inc.'s direct control affect this device and the results obtained with its use. Diros Technology Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Diros Technology Inc. neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with this device.

Diros Technology Inc. reserves the right to change specifications or to incorporate design changes without further notice and without incurring any obligations relating to equipment previously manufactured or delivered.

This document has been written in the English language. It is also available in other languages.

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10. Labeling Symbols

The following symbols can be found on product labels:

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	CONSULT INSTRUCTONS FOR USE		CAUTION
	DO NOT RE-USE		DO NOT RESTERILIZE
REF	CATALOGUE NUMBER	STERILE EO	STERILIZED USING ETHYLENE OXIDE
	DATE OF MANUFACTURE	LOT	BATCH CODE
	USE-BY DATE		MANUFACTURER
	DO NOT USE IF PACKAGE IS DAMAGED	EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
MR	MR UNSAFE		KEEP AWAY FROM SUNLIGHT
	NON-IONIZING RADIATION		TEMPERATURE LIMIT
	QUANTITY		HUMIDITY LIMITATION
Rx ONLY	CAUTION: US Federal Law restricts this device to prescription only.	⊢L⊣	DEVICE SHAFT LENGTH
Ø	DEVICE SHAFT DIAMETER	⊢ℓ⊣	DEVICE ACTIVE TIP LENGTH
CE 0413	CE MARK – EUROPEAN COMPLIANCE SYMBOL		

Note: Device active tip length ⊢ℓ⊣, is measured with tines deployed.

11. Customer Support

For any questions or additional information, please contact Customer Service at:

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